

# The Law of Toxic Substances

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**The law of toxic substances dates back to Medieval England, but the present comprehensive federal regulatory scheme was developed over the past two decades. This article presents a brief overview of the federal law of air and water pollution, solid waste control, and the regulation of chemicals.**

During the past two decades, the protection of the public and the environment from harm caused by toxic substances has received the attention of all branches of the federal government. The law of toxic substances presents a complex set of scientific, legal and practical problems. It is still in an evolutionary stage. In order to cover the essentials, I unfortunately will have to oversimplify. Time constraints compel me to ignore many related aspects of this rich topic.

It is from Medieval England that the United States obtained its common law and statutory heritage. The principal body of law governing injury due to toxic substances was the law of torts. This field of law attempts to define liability for the intentional or negligent infliction of serious bodily injury or death or destruction of property.

One important feature of this body of law is that it operated after the fact, rather than seeking to prevent harm from occurring, and it was defined largely on an *ad hoc* basis. The courts became involved after damage had occurred, and attempted on a case-by-case basis to decide whether the defendant's conduct was intentional or created an unreasonable risk of injury under the particular circumstances. Another significant feature was the principle of causation. It was considered elementary that a defendant should not be held liable unless his conduct was a cause of plaintiff's harm.

The law has changed and grown dramatically. Today it seems accepted that toxic substances comprehensively should be regulated from production and sale to consumption and disposal. Currently over two dozen separate federal environmental statutes empower four federal agencies to regulate toxic

substances. This patchwork of statutes was enacted piecemeal, mostly during the last two decades, as Congress saw particular areas that needed control. The list is all too familiar to all corporations which deal with such substances.

The Occupational Safety and Health Administration (OSHA), part of the Department of Labor, has broad responsibility under the Occupational Safety and Health Act of 1970 to regulate worker exposure to toxic substances (1). The Act establishes within the Department of Health, Education and Welfare a National Institute for Occupational Safety and Health (NIOSH) which is authorized to develop and recommend occupational safety and health standards to the Secretary of Labor.

The Food and Drug Administration (FDA) administers the Food, Drug and Cosmetic Act of 1938, together with the Food Additives Amendments of 1976 (2). The Food, Drug and Cosmetic Act establishes a comprehensive structure for the regulation of foods and substances added to foods. I would note, parenthetically, that the adulteration and misbranding of food has a long history of regulation, from biblical times to state laws enacted as early as 1784 (3).

The Consumer Product Safety Commission has power to set safety standards and labeling requirements for the sale of consumer products under the Consumer Product Safety Act of 1972 and the Federal Hazardous Substances Act of 1966 (4).

The largest share of federal regulatory responsibility in this area has been placed upon the Environmental Protection Agency (EPA). Created in 1970 through a reorganization act, EPA administers the Clean Air Act of 1970, as amended (5), the Federal Insecticide, Fungicide and Rodenticide Control Act of 1972 (6), the Federal Water Pollution Control Act

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of 1972, as amended (7), the Safe Drinking Water Act of 1974 (8), the Resource Conservation and Recovery Act of 1976 (9), and the Toxic Substances Control Act of 1976 (10).

In the present paper, I will attempt to describe some of the broad features of the federal law of air and water pollution, solid waste control, and the regulation of chemicals as administered by EPA. I will conclude with some observations on the nature of environmental decision-making.

## Air Pollution Control

Let us first look at federal control of air and water pollution.

The Clean Air Act of 1970, as amended, is divided into three parts. Title I contains the basic provisions for air pollution control from stationary sources. Title II, which I will not discuss in detail, deals with motor vehicle and fuel sources, and Title III contains general provisions relating to administrative procedure, judicial review, emergency powers, definitions and the like.

Probably the key features of the Clean Air Act are the provisions for the federal establishment of national ambient air quality standards, and the implementation of these standards through plans developed by the states and approved by EPA.

Under Section 108(a) of the Act, EPA first issues a list of pollutants which in its judgment "may reasonably be anticipated to endanger public health or welfare" (11). Thereafter under Section 109 of the Act, EPA must establish national primary and secondary ambient air quality standards. The primary standards are those that are "requisite to protect the public health," and the secondary standards are those that are "requisite to protect the public welfare." The term welfare includes effects on soils, water, crops, wildlife, climate, and property (12). To date, EPA has established national ambient standards for sulfur dioxide, particulate matter, nitrogen oxide, hydrocarbons, photochemical oxidants, carbon monoxide, and lead (13).

The national ambient standards are not themselves directly enforceable. They must be transformed into enforceable limits on emissions from specific stationary sources, such as stacks from boilers. The mechanism for this is the state implementation plan. Under this scheme, the states undertake an inventory of sources of emissions and present levels of pollutants in various air quality control regions, which generally correspond to county boundaries. The individual states then determine the amounts of cutbacks in emissions which will be imposed on various sources of pollutants within each region. The

decisions as to the mix of emission limits to be imposed involves complex scientific, economic and social factors, decisions as to which the Congress left to the states (14).

When formulated, state implementation plans are submitted to EPA for approval. EPA's approval decision is predicated upon enumerated criteria specified in Section 110(a) (2) of the Act, which requires, *inter alia*, that plans include emission limits necessary to meet the ambient standards, and adequate provisions for monitoring and enforcement. If a state plan meets these criteria, it must be approved by EPA (15). On the other hand, if EPA disapproves a plan, EPA must under Section 110(c) of the Act promulgate a plan itself unless the state submits an approvable plan within a specified time (16).

The task imposed by the 1970 Act proved difficult. The Act required attainment of the primary standards by 1975. In many areas of the country, there has been a failure to attain the national standards. The causes are many, including the fact that the ambient air quality data available were often sparse, and air quality modeling techniques used by the states were unsophisticated when the first plans were formulated in 1971.

In 1977, the Act was amended (17) to add, among others, provisions applicable to nonattainment areas, i.e., those in which the air quality does not meet national standards. Under Section 172(a) of these new provisions a state plan must provide, as a precondition for the construction or modification of any major stationary source after July 1, 1979, for attainment of the national primary standards by December 31, 1982, and the secondary standards as expeditiously as practicable (18). New sources may not be constructed in nonattainment areas, pursuant to Section 173, unless there are sufficient offsetting reductions in emissions from other sources in the area so as to represent "reasonable further progress" in achieving the standards (19). In addition, the source must comply with the "lowest achievable emission rate," and other major stationary sources owned, controlled or operated by the applicant must be in compliance or on a schedule for compliance with governing emission limits and standards. In addition to the consequences for new sources, states which fail to submit adequate plans to remedy nonattainment are subject to a loss of federal highway funds and other federal assistance under Section 176 of the amendments (20).

The 1977 amendments also codify requirements for the prevention of significant deterioration of air quality (PSD) in areas where the air is better than the national standards (21). These provisions are enforced through a detailed program of preconstruction

tion review and permits for new or modified major stationary sources. The Act establishes three area classifications for which separate incremental amounts of pollution are established (22). These increments represent an allowable increase in pollutants over a previously existing or baseline air quality levels (23). Construction of specified major new or modified sources of pollutants is regulated under a permit program requiring that the source not cause the increment to be exceeded and that the source use the best available control technology (24). EPA published its PSD regulations under the 1977 Amendments on June 19 of this year (25). A complex series of suits by industry petitioners, states and environmental groups as to the legality of these regulations is pending before the Court of Appeals (26).

Section 112 of the Clean Air Act contains a separate program for dealing with so-called hazardous air pollutants, which are defined as those which may reasonably be expected "to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness" (27). After designating such pollutants, EPA is charged with developing an emission standard at the level which in his judgement provides an ample margin of safety" (28). To date, EPA has promulgated final regulations for only four pollutants under Section 112 of the Act: asbestos, beryllium, mercury, and poly(vinyl chloride) (29).

## Water Pollution Control

The Federal Water Pollution Control Act contains parallel provisions, but in many respects different approaches to the problem of water pollution. The Act is divided into five parts: research and related programs, grants for construction of municipal treatment works, standards and enforcement, permits and licenses, and general provisions.

The principal emphasis under the Clean Water Act has been the development and enforcement of technology-based standards. The Act requires that industrial dischargers achieve by July 1, 1977, effluent limits based on the "best practicable control technology currently available," subject to the availability of a two-year extension order (30). As the second step, the Act requires the achievement of effluent limits representing the "best available technology economically achievable" by July 1, 1984, for certain enumerated toxic pollutants, and within 3 years after limits are established for other pollutants designated by EPA as either "toxic" or "non-conventional" (31).

As enacted in 1972, the Act had a quite different scheme for regulating so-called toxic pollutants. In-

stead of technology-based standards, the Act called for the development of toxic pollutant effluent standards. These standards, under Section 307(a) of the Act, were to "take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms, and the nature and extent of the effect of the toxic pollutant on such organisms" (32). This seemed a sensible approach; standards for toxic pollutants would be based on scientific information as to toxicity.

However the program soon ran into obstacles. EPA found it difficult to assemble an adequate scientific data base. There is a certain amount of laboratory bioassay data available as to the effects of certain "toxic" substances on fish, but scant field data as to the effect of these substances in the natural aquatic environment. Further, the toxicity of a given amount of a substance will depend on characteristics of the receiving water body such as flow, volume, turbidity, hardness, pH, and temperature. A standard based on one given set of water body assumptions is likely to be either overprotective or underprotective for other water bodies, yet EPA felt that it was charged with developing a single, nationwide standard. Because of these and other difficulties, EPA persuaded the Congress in 1977 to change the focus of this program to the development of technology-based standards for toxic substances (33). Although the present law authorizes EPA to develop more stringent Section 307(a) toxic pollutant standards, to date EPA has done so for only a handful of substances (34).

All of the foregoing standards are implemented through a comprehensive permit program under Section 402 of the Act. Under this program, every industrial facility must have a permit setting forth limits on pollutants which may permissibly be discharged to a water body (35).

An entirely separate program was established under Section 311 of the Act for spills of oil and hazardous substances (36). Unlike the industrial discharge program for routine industrial discharges from manufacturing processes, Section 311 is aimed at accidental or nonroutine discharges from vessels or industrial facilities. This section seeks to encourage safe handling of hazardous substances through a system of penalties and cleanup liability. Under this program, EPA designates as hazardous those substances which present "an imminent and substantial danger to the public health or welfare" when discharged (37). EPA then would determine, for each such substance, the quantity which is harmful when discharged at various "times, locations, cir-

cumstances and conditions" (38). These "harmful quantities" form the core of liability. Under Sections 311(c) and (f), whenever a hazardous substance is discharged in harmful quantities, the Federal government could take action to remove the substance from the waters, and the person responsible for the spill would be liable to the government for the costs of removal in an amount up to \$50 million in the case of onshore facilities, and \$125,000 in the case of vessels (39). The costs of removal include those for restoration and replacement of natural resources, and constitute a strong incentive for the careful handling of these substances. In addition, Section 311 imposed special penalties for hazardous substances which are determined by EPA to be nonremovable, to provide for liability in cases where cleanup liability provides little or no deterrent (40).

EPA designated 271 substances as hazardous under this program, in regulations promulgated on March 13 of this year (41). Thereafter the EPA regulations were challenged successfully by industry, and enforcement was enjoined by a district court. The court agreed with industry that EPA's harmful quantities were not related to actual harm to the environment, that EPA improperly sought to apply the regulations to routine, permitted industrial discharges, and that EPA had arbitrarily designated all 271 substances as nonremovable (42). Once again, we have a situation in which EPA has encountered difficulty in developing regulations based on the effect of substances on the environment.

In response to the court's decision, EPA asked Congress to amend this section of the Act to remedy the situation. Just before the 95th Congress adjourned, amendments to Section 311 of the Act were passed as a rider to EPA's authorization bill under the Clean Water Act (43). The 1978 amendments to Section 311 (a) eliminate the separate liability for discharges of nonremovable substances, (b) lower the penalties for discharges of hazardous substances, (c) exempt industrial discharges regulated under the NPDES permit program, and (d) delete the requirement that the Agency determine quantities which will be harmful at various times, locations and circumstances and instead allow EPA to establish by regulation those quantities which "may be harmful" to the public health and welfare. The latter provision was intended to simplify EPA's scientific task in determining harmful or reportable quantities of hazardous substances.

Under both the air and water acts, EPA has emergency power to seek to restrain pollution which presents an "imminent and substantial" danger to public health. This power is exercised in the form of a suit in a U.S. District Court (44). In general, this power has been exercised sparingly.

## Control of Solid Waste Disposal

In 1976, Congress came to grips with the simple fact that everything has to be someplace. Increasingly, pollution removed from the air and water was being disposed of on land, and there was no federal law dealing with this problem.

Congressional attention to this issue resulted in the 1976 amendments to the Solid Waste Disposal Act (45). Two major goals of the Act are to control the health related aspects of solid waste, and to reduce waste generation and encourage the recovery of resources (46).

Subtitle C of the Act establishes a "cradle to grave" system of tracking wastes. Section 3001 of the Act requires EPA to establish criteria for the identification and listing of certain wastes as hazardous, taking into account factors such as toxicity, persistence, potential for accumulation, flammability, and corrosiveness (47). Sections 3002-3004 establish a detailed system of record keeping through manifests. Generators of hazardous wastes must use appropriate containers with required labeling (48). Transporters of hazardous wastes may transport hazardous wastes only if properly labeled, and only to permitted disposal sites (49). Owners and operators of hazardous waste treatment, storage and disposal facilities are subject to EPA "performance standards" which may include "operating methods, practices and techniques," the location and design of such facilities, and reporting, monitoring and inspection and compliance with the manifest system (50).

After the effective date of regulations published by EPA, each facility for the treatment, storage or disposal of hazardous wastes must have a permit containing applicable requirements (51).

States which have qualified hazardous waste programs may issue permits for the treatment, storage and disposal of such wastes pursuant to EPA guidelines under the Act. In those states which choose not to do so, EPA will implement the program (52).

The other significant feature of the 1976 amendments is contained in Subtitle D. This subtitle contains provisions for financial assistance to states to implement comprehensive solid waste plans (53). To be eligible for grants, a state must develop a solid waste plan meeting minimum Federal criteria (54). Among these is a requirement under Section 4003 that solid waste either be utilized for resource recovery or disposed of in an environmentally sound manner. The plan must also provide within six years for the closing or upgrading of all existing open dumps to sanitary landfills under Section 4005 (55). A facility may be classified as a sanitary landfill only if there is "no reasonable probability of adverse effects on

health or the environment from disposal of solid waste at such facility" (56).

EPA is still in the process of developing the guidelines and regulations for the implementation of the 1976 amendments to the Solid Waste Disposal Act. The first set of proposed regulations was published on December 18, 1978 (57). One potential problem which has already emerged concerns the availability of qualified disposal sites. Public alarm over potential dangers from solid waste disposal has led to a refusal by communities across the country to allow new disposal sites in their areas. EPA has the authority to ban disposal to sites which do not meet standards, but claims that it is without authority to require that environmentally safe sites be available. This could be a serious regulatory gap as the program develops.

## The Toxic Substances Control Act

There is a final EPA program which I have time to mention only briefly. The Toxic Substances Control Act was adopted in 1976, and is still in the early stages of the development of regulations by EPA. The Act contains four key provisions.

Section 6 establishes EPA authority to regulate the manufacture, processing, distribution, commercial use, labeling and disposal of substances on the basis of unreasonable risk to health or the environment (58).

Section 5 requires the submission to EPA of notice and specified testing and environmental health data before the manufacture of any "new chemical substance" or the manufacture or processing of any existing chemical for a "significant new use" (59). In addition, under Section 4 EPA may order testing for any chemical substance or mixture which "may present an unreasonable risk to health or the environment" (60).

Under Section 8, EPA is presently compiling an inventory of existing chemical substances. This list will determine what substances may be manufactured without premanufacture notification. Further, under this section manufacturers, processors and distributors must maintain records and must report "immediately" any information which "reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment" (61). This program is in an embryonic stage, and it is too soon to comment on the regulatory outlook.

## Concluding Remarks

The programs which I have just described are comprehensive in the scope of their control of toxic

substances. Although I am generally optimistic as to the likelihood of success of these programs, I would note that a number of problems remain which are central to the subject of this symposium.

The first concerns the collection and interpretation of scientific information as to the toxicity of chemicals. Although I am not a scientist, my understanding, based on discussions with scientists in and outside the government, is that we have a long way to go in assembling accurate and useful information as to the thousands of chemicals which are manufactured and sold today. Equally serious problems exist concerning the scientific and regulatory definitions of harm to the environment and public health. This year, for example, the Occupational Safety and Health Administration held four months of hearings on a proposed scheme for the classification and regulatory treatment of suspected carcinogens (62). These hearings reflected the vigorous scientific debate which still exists in this area.

Secondly, the problems of the availability of cost-effective control technology or other techniques will be with us for some time. Industry continues to demand, with some persuasiveness, that federal agencies take into account the availability and costs of control devices in establishing environmental regulations. These demands are likely to become more vocal as environmental regulations become more stringent and more comprehensive. A Federal environmental program that is impossible of attainment or which imposes severe economic hardships, and that offers scant environmental benefits, is likely to be enmeshed in protracted administrative and judicial proceedings. The formulation of reasoned judgments weighing health and environmental values against economic and social interests is necessary and appropriate to assure wide public support.

The third relates to the complexity and fragmentation of the programs dealing with toxic substances. To address all sources of human exposure to a particular widely-used chemical would require action by at least four agencies under perhaps a dozen or more statutes. In many cases, the boundaries between agencies and programs are unclear. Even where jurisdiction is clear, the fragmented system discourages a comprehensive assessment of a substance's risks and benefits. No one agency has this responsibility, although such an approach might lead to different results than the sum of partial analyses. Unless a coordinated approach is developed, the prospects for duplicative and conflicting regulation by more than one Federal agency are real and problematical. One step in this direction was the formation last year of the Interagency Regulatory Liaison Group (IRLG) to improve public health through the sharing of information and developing consistent

regulatory policy. The IRLG is composed of representatives of EPA, FDA, OSHA, and the CPSC. (63).

The final problem, partially an outgrowth of fragmentation, is the absence of a uniform Federal policy for the assessment of risks of harm to the environment or public health from exposure to toxic chemicals. We cannot realistically hope to achieve a risk-free society. Needed is a rational mechanism for placing in perspective the various risks posed by various substances. One need not be a statistician to understand that the chances of being hit by an automobile are far greater than the chances of being harmed by mercury in fish. The public is becoming increasingly critical of our present *ad hoc* approach under which chemicals that present equivalent risks of harm are treated very differently.

There have been great strides in the development of laws and regulations governing toxic substances and the environment. We must be willing to reexamine these laws and regulations in light of new scientific knowledge and the experience gained in implementing them, in order to foster continued progress on these problems and public acceptance of necessary regulatory programs.

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